



HARMONIZED SYSTEM  
REVIEW SUB-COMMITTEE

-  
26<sup>th</sup> Session  
-

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(+ Annex)

O. Eng.

Brussels, 18 July 2002.

## COMPREHENSIVE REVIEW OF THE EXPLANATORY NOTES

### POSSIBLE AMENDMENT OF THE EXPLANATORY NOTE TO HEADING 29.41

(Item III.C.4 on Agenda)

#### Reference documents :

NS0060E2, Annexes A/1 and C/1 (SSC/17 – Report)  
NC0590E2, Annexes E/1 and L/2 (HSC/29 – Report)

#### I. BACKGROUND

1. The Secretariat has prepared a list of items which may require amendments to the Explanatory Notes, mainly on the basis of certain classification issues discussed at previous sessions of the Scientific Sub-Committee, and invited administrations to put forward their proposals regarding these areas as well as any other proposals they might wish to make within the framework of the comprehensive review of the Explanatory Notes (see letter No. 02NL0297-Pk/FI of 15 April 2002).
2. On 28 May 2002, the Secretariat received the following note from the **Canadian** Administration, concerning the possible amendment of the Explanatory Note to heading 29.41.

#### II. NOTE FROM THE **CANADIAN** ADMINISTRATION

3. “In the course of discussions on the classification of INN products at the Scientific Sub-Committee, several antibiotics containing the INN name stem “penem” have been discussed, most recently doripenem. These penem antibiotics are similar in chemical structure to the penicillins of subheading 2941.10 but they are excluded from that subheading by the relevant Subheading Explanatory Note. Similarly, monobactam antibiotics are structurally related to

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penicillins, however, the Subheading Explanatory Note also excludes them from subheading 2941.10.

4. To indicate that penem and monobactam antibiotics are products of heading 29.41, Canada suggests that they be listed among the examples of **other antibiotics** in the Explanatory Notes. Specifically, we propose that paragraph (7) at the bottom of page 490 of the Explanatory Notes be replaced by the following :

(7) **Other antibiotics**, e.g., sarkomycin, vancomycin, penems (e.g. doripenem) and monobactams (e.g., aztreonam)" (emphasis added).

### III. SECRETARIAT COMMENTS

5. The scope of subheading 2941.10 is clarified in the relevant Subheading Explanatory Note defining the term "penicillins" with reference to their antibiotic activity and chemical structure. In accordance with this Subheading Explanatory Note, Canada has indicated that certain antibiotics which are structurally related to penicillins, could not be classified in this subheading. In order to clarify the classification of such products, Canada proposes to insert the text "penems (e.g., doripenem) and monobactams (e.g., aztreonam)" in Item (7) of the Explanatory Note to heading 29.41 on page 490.
6. The WHO publication "The use of common stems in the selection of INNs for pharmaceutical substances" (*Programme on International Nonproprietary Names, Geneva, March 1999*) indicates that "-penem" is a stem used for analogues of penicillanic acid antibiotics modified in the five-membered ring.
7. The Subheading Explanatory Note stipulates that subheading 2941.10 is limited to such active antibiotic compounds whose penin (6-aminopenicillanic acid) skeleton in their molecule remains unmodified. The "-penem" compounds therefore could not comply with the terms of subheading 2941.10 and they should be classified in subheading 2941.90.
8. Doripenem, an example of this group of compounds cited by Canada, appears in Proposed INN List 83. The classification of doripenem was examined by the Scientific Sub-Committee at its 17<sup>th</sup> Session (see Annexes A/1 and C/1 to Doc. NS0060E2) and the Harmonized System Committee approved its classification in subheading 2941.90 (see Annexes E/1 and L/10 to Doc. NC0590E2).
9. Aztreonam, an example of monobactams, is reflected in Proposed INN List 84. The classification of this product has not been examined by the Scientific Sub-Committee in the past. According to the Merck Index (Twelfth Edition), aztreonam is the first totally synthetic monocyclic  $\beta$ -lactam (monobactam) antibiotic. Since it does not contain the unmodified penin skeleton in the molecule, its classification in subheading 2941.90 seems to be appropriate.
10. The Secretariat could support the Canadian proposal. However, the Secretariat is uncertain whether it would be suitable to use the WHO stem "penems" in the proposed text. Furthermore, the Secretariat has no information as to whether doripenem or aztreonam are significant enough in international trade in order for them to be reflected in the Explanatory Notes.
11. On the basis of the Canadian proposal, the Secretariat has prepared a proposed amendment to the Explanatory Note to heading 29.41, which is reproduced in the Annex to this document.

12. Taking into account the fact, that doripenem and aztreonam are included in Proposed INN Lists (83 and 84, respectively), the Secretariat would propose that the reference to “(INN)” be inserted after the names of products in the Explanatory Note.

#### IV. CONCLUSION

13. The Review Sub-Committee is invited to consider the proposed amendment of the Explanatory Note to heading 29.41, taking into account the note from the Canadian Administration and the Secretariat comments above.

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